

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION (TOLEDO)

TINA BURRIS,) CASE NO. 3:20-cv-01450
Plaintiff,)
v.) JUDGE JAMES R. KNEPP II
ETHICON, INC., et al.,)
Defendants.) **DEFENDANTS' OPPOSITION TO**
) **PLAINTIFF'S MOTION FOR NEW**
) **TRIAL**
)
)

I. INTRODUCTION

An imposing hurdle faces plaintiffs who request a new trial based on a single alleged evidentiary error. Not only must Plaintiff establish that the trial court committed a “clear error in judgment,” but also that the error affected the outcome of the trial such that it was not “harmless”. *Cummins v. BIC USA, Inc.*, 727 F.3d 506, 510 (6th Cir. 2013). Plaintiff can establish neither of these things.

First, this Court should disregard Plaintiff’s argument that Ethicon blindsided Plaintiff with the Surgeon’s Monograph, Exhibit 1156 (“the Monograph”) by failing to disclose it as evidence on which Ethicon would rely to show warnings information provided to Prolift implanters. The record shows otherwise. Ethicon informed Plaintiff’s counsel that the Monograph would form part of its defense in this case multiple times, during fact and expert discovery, before and after remand. Some of these disclosures date back *nine years* before trial.

Second, this Court did not commit a clear error in judgment when it admitted the Monograph into evidence through the testimony of Ethicon’s expert, Dr. Larry Sirls. Dr. Sirls authenticated the Monograph as part of Ethicon’s professional education materials used to train pelvic floor surgeons prior to April 2008, when Plaintiff’s implanting surgeon, Dr. Desrene Brown,

attended an Ethicon-sponsored Prolift cadaver lab training. *See* Pl.’s Mem. in Supp. of Mot. for New Trial, Doc. 257-1, at 3. Plaintiff attacks the foundation laid by Dr. Sirls, arguing that his recollection of when the Monograph was published was flawed. But her arguments ring hollow in light of testimony provided by Dr. Sirls on both cross-examination and re-direct confirming that the Monograph was published *in 2007*, and therefore before Dr. Brown’s Ethicon-provided training in April 2008. Moreover, even if admission of the Monograph through Dr. Sirls *was* an error—and it was not—Plaintiff cannot meet her burden of proving that it affected the outcome of the trial because the Monograph could have entered evidence through Ethicon’s other expert, Dr. Salil Khandwala, who also testified that it was part of Ethicon’s professional education materials in April 2008.

Plaintiff, therefore, cannot meet her burden of proving that the Court committed a clear error of judgment in admitting the Monograph, let alone that doing so prejudiced her by substantially affecting the outcome of this case. This Court should therefore deny her Motion.

II. LAW AND ARGUMENT

A. A new trial is appropriate only if Plaintiff can establish that the Court’s admission of the Monograph was a “clear error in judgment” affecting the outcome of the trial.

The only basis for a new trial cited by Plaintiff is the Court’s admission of the Monograph, which Ethicon made available to pelvic floor surgeons during its professional education courses. Evidentiary rulings are “not to be lightly overturned.” *Cummins*, 727 F.3d at 510. Obtaining a new trial based on an evidentiary ruling “is particularly difficult because both the denial of a new trial and the evidentiary ruling will be reviewed for abuse of discretion.” *In re National Prescription Opiate Litig.*, MDL 2804, 2022 WL 668434, at *22 (N.D. Ohio Mar. 7, 2022) (citing *Jones v. Wiseman*, 838 F. App’x 942, 945-46 (6th Cir. 2020)); *see also Cummins*, 727 F.3 at 509 (“To the

extent the motion for new trial was based on an erroneous evidentiary ruling, the evidentiary ruling, too, is evaluated under the abuse-of-discretion standard.”). The Sixth Circuit will find an abuse of discretion only where it is left with a “definite and firm conviction that the trial court has committed a clear error of judgment.” *United States v. Thompson*, 501 F. App’x 347, 363 (6th Cir. 2012). Additionally, a party seeking a new trial based on an evidentiary ruling must surmount the additional hurdle of showing that the error “affected the outcome of the trial.” *Cummins*, 727 F.3d at 510 (“An erroneous evidentiary ruling amounts to reversible error, justifying a new trial, only if it was not harmless; that is, only if it affected the outcome of the trial.”).

B. Contrary to what Plaintiff has argued, Ethicon produced the Monograph in discovery and disclosed it as a basis for the opinions of two of Ethicon’s expert witnesses, Dr. Sirls and Dr. Khandwala.

This Court should disregard Plaintiff’s accusations that Ethicon blindsided her counsel with the Monograph by failing to disclose it either during the general, pre-remand discovery in MDL 2327 or as a basis for Dr. Sirls’s opinions. On the contrary, Ethicon notified Plaintiff multiple times over the course of discovery, in both fact and expert discovery, before and after remand, that the Monograph was part of the evidence that it would use to defend its warnings.

First, Plaintiff incorrectly claims that Ethicon did not disclose the Monograph in response to a pretrial interrogatory propounded by plaintiffs in the MDL and “aimed at discovering what warnings information Ethicon provided to physicians.” Pl.’s Mem. in Supp., Doc. 257-1, at 3. Plaintiff directs the Court to Ethicon’s Third Supplemental Response to Plaintiffs’ First Set of Interrogatories, served on August 9, 2013. *Id.* But contrary to Plaintiff’s representation, Ethicon’s Third Supplemental Response *does* disclose the Monograph. Specifically, Ethicon’s Supplemental Response to Interrogatory 2, which inquires about the warnings, information, or notifications provided to health care providers, discloses bates range “ETH.MESH.03456774-ETH.MESH

03461142 (Prod. 34)"—a range which includes the Monograph, which is labeled ETH.MESH.03460813-03460853. *Compare* Pl.'s Ex. A, Doc. 257-2, at 4 *with* Exhibit 1. The Monograph was thus disclosed *almost nine years prior to trial* as part of the warnings that Ethicon provided to physicians, and Plaintiff suffered no prejudice or undue surprise by Ethicon's utilization of it at trial for that very purpose.¹ This is particularly the case here, where Ethicon again disclosed Exhibit 1156, the Monograph, in the Exhibit List appended to Defendants' Trial Brief as Appendix A, which was filed more than a month before trial on June 3, 2022. *See* Doc. 200-4 at 6 (PageID #: 14559); *see also id.* at 7 (PageID #: 14560) (disclosing 2007 Surgeon's Monograph as Ex. 1163).

Second, contrary to Plaintiff's argument in her motion, she had been on notice that Dr. Sirls, may testify about the Monograph since receiving his February 11, 2017 General Expert Report, which was disclosed in this case on September 18, 2019. In that Report, Dr. Sirls offered the following opinion about Ethicon's professional education materials:

It is my opinion that the training and professional education for the Prolift system was well done, informative, and conveyed known risks of the Prolift system and other pelvic floor surgeries including dyspareunia and voiding dysfunction.

General Expert Report of Larry T. Sirls, M.D. ("Sirls Report") (Feb. 11, 2017) at 53, Doc. 257-3 (PageID #: 20012). Dr. Sirls's Report put Plaintiff's counsel on notice that he would testify about the materials used by Ethicon in its professional education efforts, which includes the Monograph. The Monograph was specifically identified in the list of materials relied on by Dr. Sirls as the basis for his opinions that was disclosed to Plaintiff in September 2019. Larry Sirls General Materials

¹Because Plaintiff did not raise this objection to the Monograph's admissibility at trial, her objection as to the Monograph's admissibility on this particular ground is subject to review only for "plain error." *See United States v. Deitz*, 577 F.3d 672, 688 (6th Cir. 2009) ("[W]here a defendant fails to object at trial or 'does not state the specific ground for his evidentiary objection, and that ground is not apparent from the context, we review a newly raised objection under the plain-error standard.'").

List in Addition to Materials Referenced in Report at 99 (disclosing the “2007 Prolift Surgeon Monograph”), attached as Exhibit 2.

Third, even if Plaintiff could plead ignorance of Dr. Sirls’s reliance on the Monograph, she was not ambushed by its relevance to the warnings issue in this case because it was explicitly addressed in the report prepared by Ethicon’s other expert, Dr. Salil Khandwala, who wrote in his case-specific report:

As I discuss in my expert report, Prolift has an acceptable low rate of erosion in light of the benefit it provides the surgeon and the patient. It’s also important to note that mesh erosion is warned about in the Prolift IFU, Surgeon’s Monograph and Ethicon professional education materials.

Case Specific Report of Salil Khandwala, M.D. (“Khandwala Report”) (Sept. 9, 2019) at 10, attached as Exhibit 3.

C. The Monograph was properly admitted during the testimony of Dr. Larry Sirls.

Plaintiff does not contest the relevance of the Monograph to the issue of what warnings and professional education Ethicon provided to Prolift implanters, including surgeons like Plaintiff’s implanter, Dr. Brown. *See* Doc. 257-1 at 8. Rather, her sole objection to the Monograph’s admissibility is that Dr. Sirls failed to establish a sufficient foundation. *See id.* Yet, Dr. Sirls unequivocally testified that the Monograph was among the professional education materials that Ethicon provided at Prolift training sessions and which he himself used as a training resource. *See* Tr. Vol. 6 at 1139:6-1140:11.

Plaintiff’s argument that Dr. Sirls “recanted” his testimony about its publication date, Doc. 257-1 at 1, does not undo the foundation for the Monograph. Plaintiff has not identified anything to undercut Dr. Sirls’s testimony that the Monograph was part of the professional education materials published by Ethicon and made available at its seminars and courses. At most, Dr. Sirls

clarified that he was confused about dates. *See* Tr. Vol. 6 at 1204:9-12 (“My dates were wrong, but the information that I had at my fingertips at that time was this information. I just have the wrong dates. It’s a long time ago. I’m sorry.”). Upon re-direct examination, he confirmed that the Monograph was published *in 2007*. *See id.* at 1232:20-1234:8. Therefore, Dr. Sirls’s testimony established that the Monograph was part of Ethicon’s Prolift professional education materials prior to the April 2008 cadaver lab attended by Dr. Brown.

D. Even if Plaintiff could establish that the Court erred in admitting the Monograph through the testimony of Dr. Sirls, any such error is harmless and not reversible because the Monograph could have been admitted through the testimony of Dr. Khandwala.

Plaintiff has not established that the Court erred in admitting the Monograph into evidence through Dr. Sirls, but even if she *could*, she cannot establish that any such error “affected the outcome of the trial,” which is the hurdle she must clear to obtain a new trial. *See Cummins*, 727 F.3d at 510. At best, she hypothesizes that the jury *might* have found Ethicon’s warnings inadequate had the Monograph not come into evidence. But in making this assumption, Plaintiff ignores the testimony of Ethicon’s other expert, Dr. Khandwala, who *also* testified about the Monograph, its publication, and its role as part of Ethicon’s professional education materials. Had the Monograph not come into evidence through Dr. Sirls, it could have been admitted through Dr. Khandwala.

As explained above, Dr. Khandwala also relied on the Monograph as a basis for his opinions about Ethicon’s warnings to pelvic floor surgeons through its professional education, even mentioning it in the body of his report. Ex. 3, Khandwala Report at 10. He also testified at trial that the monograph was published in April 2007 and would have been available to any physicians taking training courses sponsored by Ethicon before August of 2008:

Q. And did this, in part, then reflect the state of the science with respect to prolapse repair with Prolift at the time this was published?

A. This is just part of it.

Q. And again, what was the date that the monograph was published?

A. 2007, April.

Q. So it would have been available to anybody taking training before August of 2008?

A. Correct. After 2007, before 2008.

Tr. Vol. 7 at 1478:14-23. Any error in admitting the Monograph through Dr. Sirls was therefore “harmless” because the same evidence could have come in, for the same purpose, through Dr. Khandwala.

When challenging a defense verdict in a Motion for New Trial, “Plaintiff bears the burden of showing an error was *not* harmless.” *Jones v. Sandusky County, Ohio*, 96 F. Supp.3d 711, 716 (N.D. Ohio 2015) (emphasis added) (citing *Varga v. Rockwell Intern. Corp.*, 242 F.3d 693, 701-02 (6th Cir. 2001)). But Plaintiff does not address—let alone argue against—whether the Monograph could have been admitted into evidence through Dr. Khandwala as opposed to Dr. Sirls. Nor can Plaintiff prove that admission of the Monograph affected the outcome of the trial. Plaintiff speculates that the Monograph swayed the jury to find against Plaintiff on the question of warnings adequacy, *see* Doc. 257-1 at 8, but it is possible that a reasonable jury could have found against her on this issue even *without* the Monograph. Nor does Plaintiff contest the fact that there are other elements of her burden of proof, such as causation—a jury interrogatory that the jury did not even reach given its finding on warnings adequacy—on which the jury may have found against her. It is thus impossible for Plaintiff to prove that admission of the Monograph prejudiced her in a way that substantially affected the outcome of the trial. *See Cummins*, 727 F.3d at 510 (“An erroneous evidentiary ruling amounts to reversible error, justifying a new trial, only if it was not harmless; that is, only if it affected the outcome of the trial.”).

III. CONCLUSION

As the Sixth Circuit has explained, evidentiary rulings are “not to be lightly overturned,” and still more rarely amount to grounds for a new trial. *Cummins*, 727 F.3d at 510. Plaintiff was not blindsided or unfairly prejudiced by Ethicon’s use of the Monograph, which it had disclosed to Plaintiff multiple times, in multiple ways, before trial. In addition, this Court did not err by admitting the Monograph into evidence through the testimony of Dr. Sirls, who laid an adequate foundation for it as part of Ethicon’s professional educational materials. Moreover, even if this Court *did* err in admitting the Monograph through Dr. Sirls, the same document could have come into evidence through Ethicon’s other expert, Dr. Khandwala, which Plaintiff does not even contest. For these reasons, Plaintiff cannot establish an evidentiary error requiring a new trial under Fed. R. Civ. P. 59, and this Court should deny her Motion.

Respectfully submitted,

/s/ Erica M. James

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CERTIFICATE OF SERVICE

I hereby certify that on September 1, 2022, a copy of the foregoing was filed electronically.

Service of this filing will be made by operation of the Court's electronic filing system.

/s/ Erica M. James

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